

MAR 19 2002

Freedom of Information Summary

NADA 121-473

Supplemental New Animal Drug Application

Intervet Inc.
405 State Street
PO Box 318
Millsboro, DE 19966-0318

PANACUR[®]-C (fenbendazole) Granules 22.2%

This supplement provides for a change from prescription (Rx) to OTC status for fenbendazole granules 22.2% packets to be marketed under the trade name PANACUR[®]-C.

1. GENERAL INFORMATION

Supplemental New Animal Drug Application No.: 121-473

Sponsor: Intervet Inc.
405 State Street
PO Box 318
Millsboro, DE 19966-0318

Generic Name of Drug: Fenbendazole

Trade Name: PANACUR®-C

Marketing Status: Over-the-Counter (OTC)

Effect of Supplement: This supplement provides for a change from prescription (Rx) to OTC status for fenbendazole granules 22.2% packets to be marketed under the trade name PANACUR®-C. The jar presentation (Panacur®) will remain prescription (Rx) as it is also labeled for use in other species of carnivorous/omnivorous animals. The jar presentation will continue to be marketed under the Panacur® trade name.

2. INDICATIONS FOR USE

PANACUR®-C granules are indicated for use in adult dogs (including pregnant bitches) and puppies, six weeks of age or older, for the treatment and control of roundworms (*Toxocara canis*, *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*) and tapeworms (*Taenia pisiformis*).

3. DOSAGE FORM

Granules 22.2% (222 mg/g) for oral use

4. ROUTE OF ADMINISTRATION

PANACUR®-C granules should be mixed with a small amount of the usual food. Make sure the dog eats all of the medicated food. Dry dog food may need to be moistened to aid mixing.

5. RECOMMENDED DOSAGE

The daily dose for PANACUR®-C is 50 mg/kg (22.7 mg/lb.) of body weight. PANACUR®-C is packaged in three packet sizes (1g, 2g and 4g) for administration based on the weight of the dog (see Dosing Table below). Weigh the dog to make sure the right size and number of packets are used. If the dog's weight is in-between the suggested dosing sizes, it is safe to use the next higher size. For example, a 15-pound dog should be treated with the 2-gram packet. Packet size is the daily dose and the dog must be treated with this dose for three (3) days in a row.

Dosing Table

Dog Weight	Packet Size
10 pounds	1 gram
20 pounds	2 gram
30 pounds	1 gram + 2 gram
40 pounds	4 gram
50 pounds	1 gram + 4 gram
60 pounds	2 gram + 4 gram
80 pounds	Two 4 gram
Over 80 pounds	Use combinations to obtain recommended daily dose.

6. EFFECTIVENESS

The effectiveness of the product is not affected by this supplement. Refer to the FOI Summary for the original approval dated 27 October 1983.

7. SAFETY

The safety of this product is not affected by this supplement. Refer to the FOI Summary for the original approval dated 27 October 1983.

8. HUMAN SAFETY

Data on human safety pertaining to the consumption of drug residues in food were not required for approval of this supplemental NADA. The product is labeled for use in dogs, which are non-food animals.

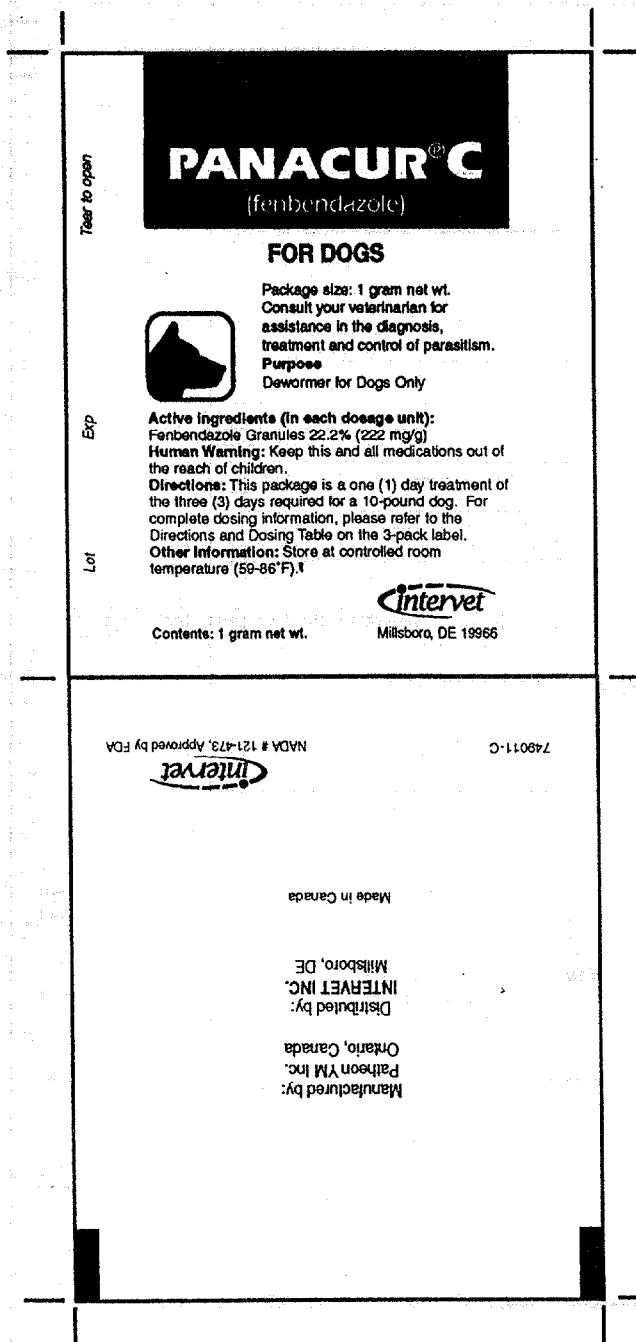
9. AGENCY CONCLUSIONS

The data in support of this NADA comply with the requirements of Section 512 of the Act and Part 514 of the implementing regulations. The data demonstrate that Panacur (fenbendazole) Granules 22.2%, when used under labeled conditions is safe and effective.

At the time of original approval this drug product received prescription status because of concern that fenbendazole may have some undiscovered hepatotoxic effects in dogs. This concern was based on reports of liver disease associated with the use of oxibendazole and mebendazole in dogs. The restriction to prescription status was intended to assist in timely notification/documentation of such adverse reactions should they occur. Post-approval marketing experience has not demonstrated a pattern of liver disease associated with the use of Panacur (fenbendazole) Granules 22.2% in dogs. Since the safety concern has been satisfied, and adequate directions for safe and effective use can be written for the layman, there is no longer a need for prescription status for use of this product in dogs.

10. LABELING

PANACUR[®]-C – 1-gram packet label
PANACUR[®]-C – 3 x 1-gram box label
PANACUR[®]-C – 2-gram packet label
PANACUR[®]-C – 3 x 2-gram box label
PANACUR[®]-C – 4-gram packet label
PANACUR[®]-C – 3 x 4-gram box label



FRONT

FOR
INDICATION ONLY
LINE DOES NOT PRINT

BACK

6-00 • Panacur 1 gram Granule Pouch Label •
• Size: 2.3/4"x6.9/16" •

PMS COLORS

Pantone 328

Black

Yellow

PANACUR® C

(fenbendazole)

FOR DOGS



Package contents: Three 1-gram packets
Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Drug Facts

Active ingredients (in each dosage unit):

Fenbendazole Granules 22.2% (222 mg/g)

Purpose: Dewormer for Dogs Only

Uses: For the treatment and control of Roundworms (*Toxocara canis*, *Toxascaris leonina*), Hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), Whipworms (*Trichuris vulpis*), and Tapeworms (*Taenia pisiformis*).

Human Warning: Keep this and all medication out of the reach of children.

Adverse Reactions: In US clinical studies 3 of 240 dogs (about 1% of the treated dogs) had vomiting associated with use of the product.

When using this product: PANACUR® C is safe for use in puppies 6 weeks or older and adult dogs, including pregnant bitches. Do not deworm a dog or puppy that is sick. Consult your veterinarian for diagnosis of the illness.

Contents: Three 1-gram packets



Directions
The daily dose for PANACUR® C is 50 mg/kg (22.7 mg/lb) of body weight. Please refer to the following dosing table for help in finding the right dose for your dog.

Dosing Table

Dog Weight	Packet Size
10 pounds	1 gram
20 pounds	2 gram
30 pounds	1 gram + 2 gram
40 pounds	4 gram
50 pounds	1 gram + 4 gram
60 pounds	2 gram + 4 gram
80 pounds	Two 4 gram
Over 80 pounds	Use combinations to obtain recommended daily dose.

Other Information:
• Repeat the daily dose for three days in a row.
• Give PANACUR® C to your dog by mixing the daily dose with a small amount of the usual food. Make sure your dog eats all of the medicated food. You may need to moisten dry dog food to aid mixing.
• You should weigh your dog to make sure you are using the right size and number of packets. If your dog's weight is between the suggested dosing sizes, it is safe to use the next higher size. For example, a 15-pound dog should be treated with the 2-gram packet.
• PANACUR® C only kills *Taenia* species of tapeworms. If you continue to see tapeworm segments in your dog's stool after treatment with PANACUR® C, consult your veterinarian.
• Recommended Deworming Schedule: Deworming schedules may vary depending on the climate where you live and the activity of your dog. The following schedule should be used as general guidance. Newly weaned pups (6 to 8 weeks of age) should be dewormed at 8, 9, 10, and 12 weeks of age. Treat the dam at the same time as the puppies. Dogs over six months of age should be dewormed at least twice each year. Each deworming requires 3 daily treatments. (See Directions)

Diagnosis of Parasites: Specific diagnoses require laboratory testing. Consult your veterinarian for help in the diagnosis, treatment, and control of parasitism. Dogs can become infected with several different kinds of tapeworms. PANACUR® C only kills *Taenia* species of tapeworms. If you continue to see tapeworm segments in your dog's stool after treatment with PANACUR® C, consult your veterinarian.

Recommended Deworming Schedule: Deworming schedules may vary depending on the climate where you live and the activity of your dog. The following schedule should be used as general guidance. Newly weaned pups (6 to 8 weeks of age) should be dewormed at 8, 9, 10, and 12 weeks of age. Treat the dam at the same time as the puppies. Dogs over six months of age should be dewormed at least twice each year. Each deworming requires 3 daily treatments. (See Directions)

Questions? Comments?
To report a suspected adverse reaction or to obtain product information including material safety data sheets (MSDS), call 1-800-328-5908.

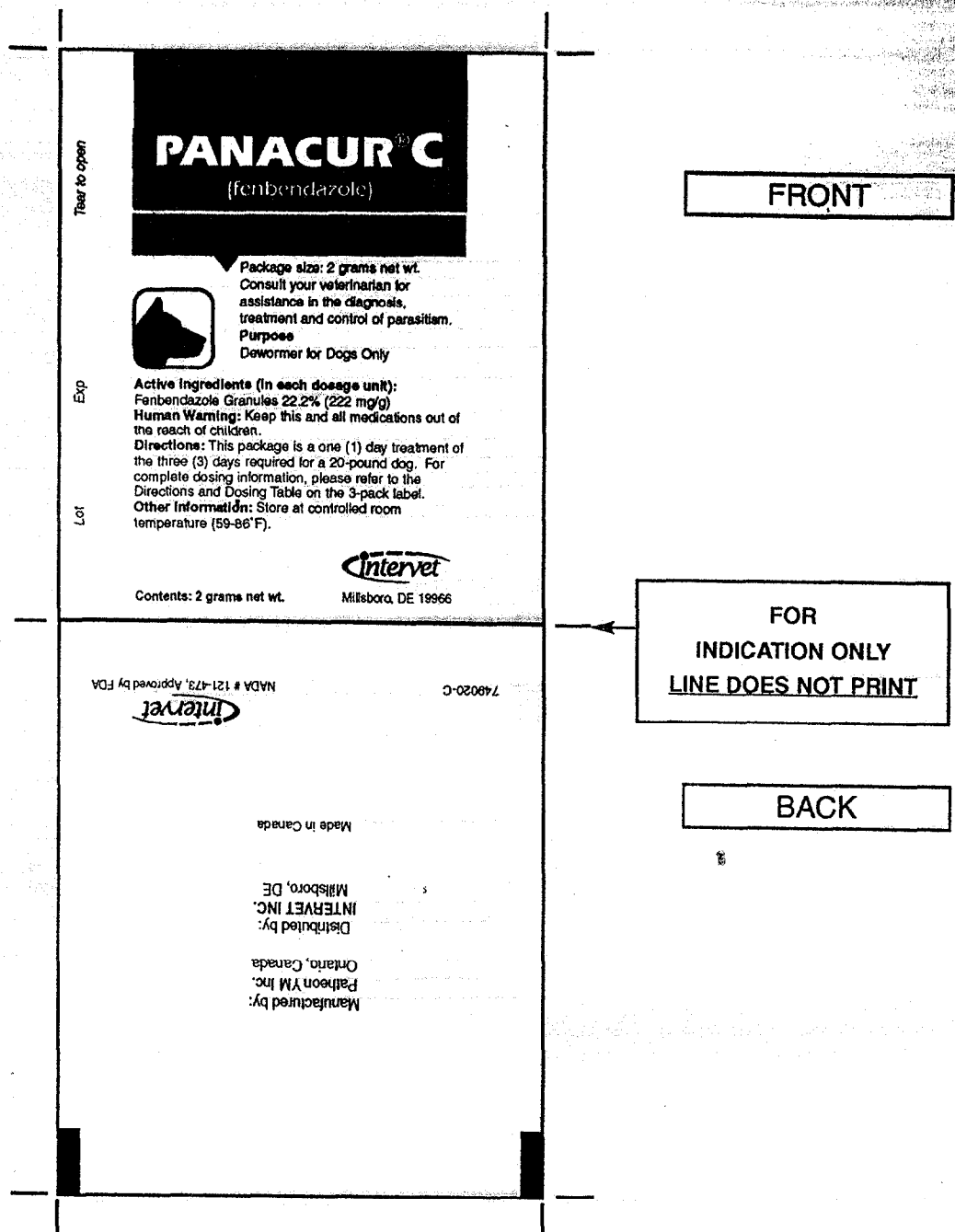
Storage: Store at controlled room temperature (59-86°F).

Manufactured by:
Patterson V.M. Inc.
Ontario, Canada

Distributed by:
INTERVET INC.
Millsboro, DE

Net Weight: 3 grams

Expiration date:
Lot number:
NADA # 121-473, Approved by FDA



6-00 • Panacur 2 gram Granule Pouch Label •
• Size: 2.3/4"x6.9/16" •

PMS COLORS

Pantone 328

Black

Blue

PANACUR® C

(fenbendazole)



Package contents: Three 2-gram packets
Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Drug Facts

Active Ingredients (In each dosage unit):

Fenbendazole Granules 22.2% (222 mg/g)

Purpose: Dewormer for Dogs Only

Uses: For the treatment and control of Roundworms (*Toxocara canis*, *Toxascaris leonina*), Hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), Whipworms (*Trichuris vulpis*), and Tapeworms (*Taenia pisiformis*).

Human Warning: Keep this and all medication out of the reach of children.

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When using this product: PANACUR® C is safe for use in puppies 6 weeks or older and adult dogs, including pregnant bitches. Do not deworm a dog or puppy that is sick. Consult your veterinarian for diagnosis of the illness.

Contents: Three 2-gram packets



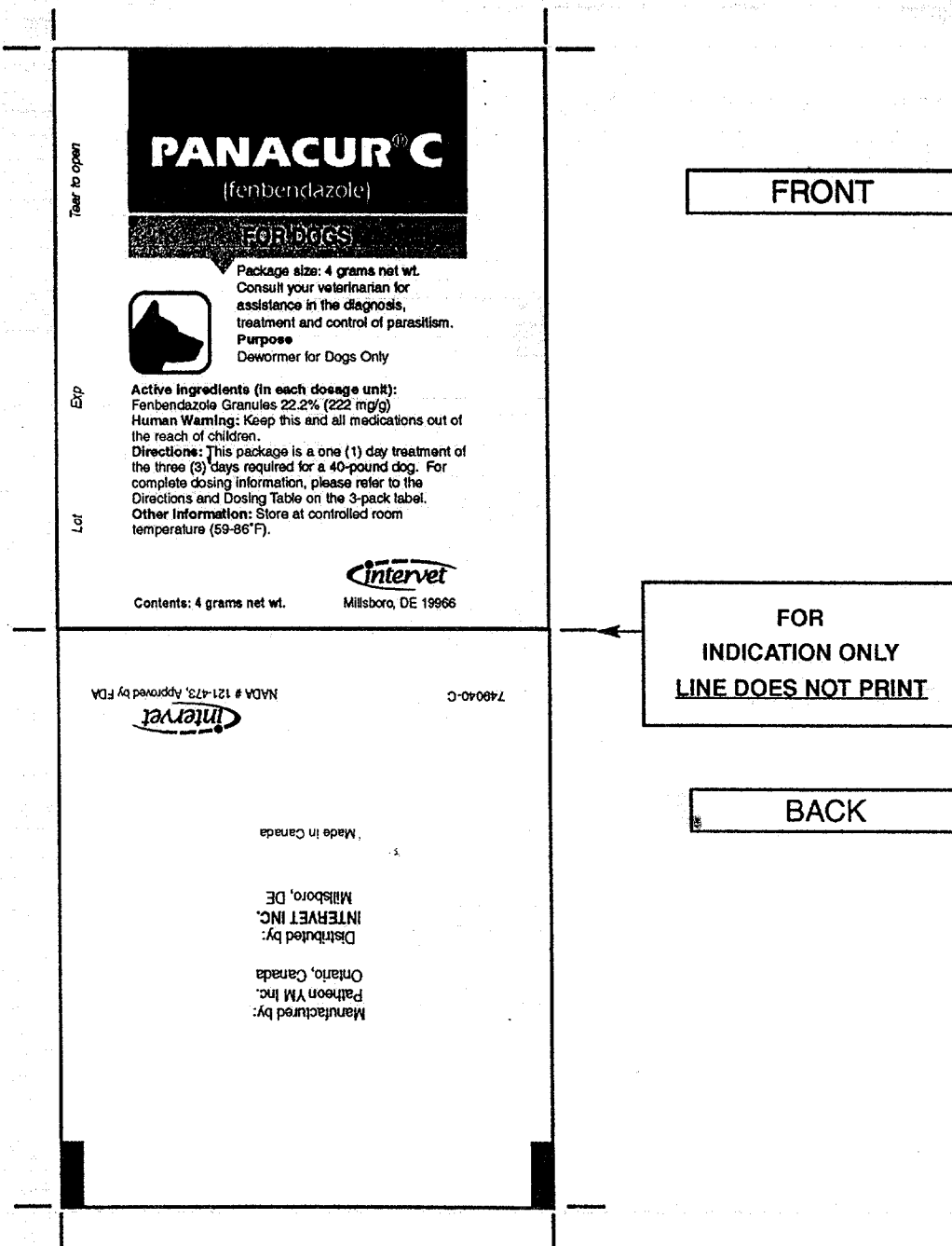
Made in Canada
Ontario, Canada
Pathcon YMI Inc.
Manufactured by:
To report a suspected adverse reaction or to obtain product information including material safety data sheets (MSDS), call 1-800-326-6908.
Distributed by:
INTERVET INC.
Millboro, DE
NADA # 121-473, Approved by FDA
Expiration date:
Lot number:

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• Give PANACUR® C to your dog by mixing the daily dose with a small amount of the usual food. Make sure your dog eats all of the medicated food. You may need to moisten dry dog food to aid mixing.
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Packet size is the daily dose. The dog must be treated with this dose for 3 days in a row.

Dog Weight	Packet Size
Over 80 pounds	Use combinations to obtain
80 pounds	Two 4 gram
60 pounds	2 gram + 4 gram
50 pounds	1 gram + 4 gram
40 pounds	4 gram
30 pounds	1 gram + 2 gram
20 pounds	2 gram
10 pounds	1 gram

The daily dose for PANACUR® C is 50 mg/kg (22.7 mg/lb.) of body weight. Please refer to the following dosing table for help in finding the right dose for your dog.



6-00 • Panacur 4 gram Granule Pouch Label •
• Size: 2.3/4"x6.9/16" •

PANACUR® C

(fenbendazole)

FOR DOGS



Package contents: Three 4-gram packets
Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Drug Facts

Active Ingredients (In each dosage unit):

Fenbendazole Granules 22.2% (222 mg/g)

Purpose: Dewormer for Dogs Only

Uses: For the treatment and control of Roundworms (*Toxocara canis*, *Toxascaris leonina*), Hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), Whipworms (*Trichuris vulpis*), and Tapeworms (*Taenia pisiformis*).

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Contents: Three 4-gram packets

intervet

NADA #121-473, Approved by FDA

intervet

Lot number:
Expiration date:

Net Weight 12 grams

Distributed by:
INTERVET INC.
Millsboro, DE

Made in Canada
Ontario, Canada
Manufactured by:
Pathon Ym Inc.

To report a suspected adverse reaction or to obtain product information including material safety data sheets (MSDS), call 1-800-328-5908.

Questions? Comments?

Storage: Store at controlled room temperature (59-86°F).

Directions

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